

NOV 19 2004

Smith & Nephew, Inc.  
Summary of Safety and Effectiveness  
Smith & Nephew Modular Hip

**Contact Person and Address**

Janet Johnson Akil  
Director, Regulatory Affairs  
Smith & Nephew, Inc.  
Orthopaedic Division  
1450 Brooks Road  
Memphis, TN 38116  
(901) 399-5153

Date of Summary: November 2, 2004

**Name of Device:** Smith & Nephew Modular Hip**Common Name:** Prosthetic hip joint**Device Description**

The Smith & Nephew Modular Hip consists of primary and revision stems used with porous and HA coated modular sleeves. The stems feature a 12/14 taper and are used with existing Smith & Nephew femoral heads and acetabular components. Modular hip stems and sleeves are manufactured from Ti-6Al-4V conforming to ASTM F 1472 or ASTM F 136.

**Device Classification**

21 CFR 888.3353 Hip joint metal/ceramic/polymer semi-constrained cemented or nonporous uncemented prosthesis – Class II

**Mechanical and Clinical Data**

A review of the mechanical test data indicated that the Smith & Nephew Modular Hip is equivalent to devices currently used clinically and is capable of withstanding expected *in vivo* loading without failure.

**Indications for Use**

Total hip components are indicated for uncemented use in individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity. Smith & Nephew Modular Hip components are for single use only.

**Substantial Equivalence Information**

The substantial equivalence of the Smith & Nephew Modular Hip is based on its similarities in indications for use, design features, operational principles, and material composition to the following predicate devices – Joint Medical Products S-ROM Total Hip System (K921111, K934412, K954935, and K961939) and the Smith & Nephew Synergy Hip System (K963509, K991485, and K002996).



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Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Jason Sells  
Regulatory Affairs Specialist  
Orthopaedics  
Smith & Nephew, Inc.  
1450 Brooks Road  
Memphis, Tennessee 38116

Re: K042127

Trade Name: Smith & Nephew Modular Hip  
Regulation Number: 21 CFR 888.3353  
Regulation Name: Hip joint metal/ceramic/polymer semi-constrained cemented or  
nonporous uncemented prosthesis  
Regulatory Class: II  
Product Code: MEH  
Dated: August 5, 2004  
Received: August 6, 2004

Dear Mr. Sells:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

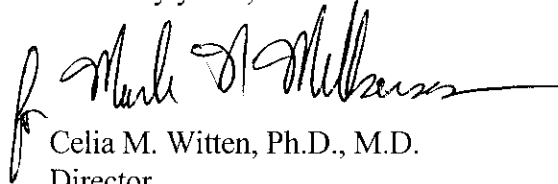
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Celia M. Witten", with a long horizontal flourish extending to the right.

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K042127

Device Name: Smith & Nephew Modular Hip

### Indications for Use:

Total hip components are indicated for uncemented use in individuals undergoing primary and revision surgery where other treatments or devices have failed in rehabilitating hips damaged as a result of trauma, inflammatory joint disease such as rheumatoid arthritis, or noninflammatory degenerative joint disease (NIDJD) or any of its composite diagnoses such as osteoarthritis; avascular necrosis; traumatic arthritis; slipped capital epiphysis; fused hip; fracture of the pelvis; diastrophic variant; old, remote osteomyelitis with an extended drainage-free period; nonunion, femoral neck fracture and trochanteric fractures of the proximal femur with head involvement that are unmanageable using other techniques; femoral osteotomy, or Girdlestone resection; fracture dislocation of the hip; and correction of deformity. Smith & Nephew Modular Hip components are for single use only.

Prescription Use X  
(Part 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

*for Mark J. Millman*  
(Division Sign-Off)  
Division of General, Restorative,  
and Neurological Devices

510(k) Number K042127

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